

**REMARKS**

The Examiner responds to Applicants' Appeal Brief by reopening prosecution.<sup>1</sup> The Examiner provides two rejections as listed below.

- I. Claims 1, 3-13, and 15-17 are rejected under 35 USC § 102(e) as allegedly being anticipated by Anderson *et al.*, United States Patent No. 5,922,591.
- II. Claims 1 - 20 are rejected under 35 USC § 102(e) as allegedly anticipated or, in the alternative, under 35 USC § 103(a) as obvious over Anderson *et al.* United States Patent No. 5,922, 591.

**I. Anderson *et al.* Is Not Prior Art**

The Examiner has improperly relied upon Anderson *et al.* as prior art. The Examiner is reminded that the present application has a September 15, 1995 priority date. Consequently, neither Anderson *et al.* (Filed: June 27, 1996) or Anderson's priority patent (Lipshutz *et al.*, United States Patent No. 5,856,174, Filed: January 19, 1996) are prior art. Further, the Examiner has not considered whether these rejections are supported by Lipshutz's priority applications consisting of two provisional applications 60/000,703 (Filed: June 29, 1995) and 60/000,859 (Filed: July 3, 1995). Since Anderson *et al.* is a Continuation-In-Part application, it contains new matter and this new matter is entitled only to the June 27, 1996 date - which is well after the priority date of the present case. Indeed, a careful analysis shows the Examiner has relied on new matter in Anderson *et al.* relative to Lipshutz *et al.* that is not supported by the priority dates of the two provisional applications.<sup>2</sup>

The following examples demonstrate that the Examiner is relying on the new matter within Anderson *et al.* For example;

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<sup>1</sup> Applicants note that the Office Action was not co-signed by the Examiner's Supervisor.

<sup>2</sup> It stands to reason that matter in Anderson *et al.* that is not found in Lipshutz *et al.* is also not in the provisional applications. However, it is the Examiner's burden to confirm this.

1. *Office Action ¶ 8:* The Examiner asserts that "Figure 15A clearly depicts a device that comprises a first and second housing ...".

The Examiner is reminded that Figure 15 is new matter when compared to Lipshutz *et al.*

2. *Office Action ¶ 10:* The Examiner asserts that "Column 18, last paragraph, bridging to column 20, teach explicitly that the device may be made from silicon or glass, and that in such case, the channels may be manufactured by etching."

The Examiner is reminded that Anderson *et al.* col 18 ln 41 - col 19 ln 11 is new matter when compared to Lipshutz *et al.*

3. *Office Action ¶ 11:* The Examiner asserts that "Column 20, third paragraph, teaches coating the surface of the device with materials such as silicon oxide and Teflon, and that this can be done in conjunction with the analysis of nucleic acids ..."

The Examiner is reminded that Anderson *et al.* col 20 ln 33 - 49 (*i.e.*, 3rd paragraph) is new matter when compared to Lipshutz *et al.*

In order to establish the validity of these assertions, the Examiner must find them in the above cited provisional applications.

## **II. Lipshutz *et al.* Teaches Distinct Sample Transport And Heating Elements**

Since the Examiner has not sustained his burden to properly show the cited art is in fact, prior art, no further discussion is needed. Nonetheless, without waiving the argument, but to further prosecution, the cited art is discussed on its merits (or lack thereof).

The Examiner attempts to argue that Anderson *et al.* teaches fluid transport by differential heating:

Column 32, first paragraph, and column 35, first paragraph, teach explicitly of providing sufficient number of such heaters in the fluid channel so as to provide for "sample transport". Said "sample transport" speaks directly to the heater being in an array and create "differential heating" ... of the sample.

*Office Action ¶ 12.* The Applicants have carefully reviewed both Anderson *et al.* and Lipshutz *et al.* and find no such teaching. In fact, the Applicants cannot find within Anderson

*et al.* any sentence reciting that a "fluid channel" is arrayed with any heating element, much less a "sufficient number of such heaters in the fluid channel".<sup>3</sup> The cited art teaches fluid transport by "positive pressure" - not by "differential heating".

Lipshutz *et al.* begins (col 23 ln 38) by stating that:

In a similar aspect, a positive pressure source may be applied to the originating chamber to push the sample into subsequent chambers.

Specifically identified is a "pneumatic pressure manifold" that operates such that:

In this application, each subsequent chamber is kept at an incrementally higher pressure by the presence of the appropriate fluidic resistors and vents, as described above.

Lipshutz *et al.*, col 23 ln 53-56. Lipshutz *et al.* continues (col 24) to discuss the need for a thermopneumatic pump, in which a heater is placed within the pump's pressure chamber to heat an inert gas (*i.e.*, for example, fluorinated hydrocarbon; col 24 ln 23-24). This inert gas then pressurizes the pump pressure chamber thus moving fluid from one reaction chamber to another.

Lipshutz *et al.* then provides several operational examples that require a controllable temperature:

For example, ... amplification ... extension, transcription, and hybridization ... requires cycling ... at optimized controlled temperatures.

Lipshutz *et al.*, col 24 ln 36 - 42. The heaters contemplated by Lipshutz *et al.* are "... applied within or adjacent to a reaction chamber ..." (col 24 ln 46-47) which "... will be capable of producing temperatures in excess of 100 degrees ... " (col 24 ln 53-54). It is important to realize that Lipshutz *et al.* describes, in detail, the placement of these heaters on the surface of reaction chambers which control only the temperature of the reaction chamber contents (col 24 ln 59 - col 25 ln 6). Lipshutz *et al.* follows this discussion with a description of miniature temperature sensors to control the reaction parameters within the reaction chamber (col 25 ln 7 - 41).

The above description within Lipshutz *et al.* provides the technical background for the following summary paragraph:

In addition to fluid transport and temperature control elements, one or more of the reaction chambers of the device may also incorporate a mixing function. For a

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<sup>3</sup> The Examiner makes these statements without any citation to actual text or line numbers in the cited specification.

number of reaction chambers, mixing may be applied merely by pumping the sample back and forth into and out of a particular reaction chamber.

*Lipshutz et al.* col 25 ln 42-47. Read in the context of the preceding four paragraphs of text in columns 23 and 24 (which Applicants have discussed above), the first sentence in the above passage clearly identifies that fluid transport and temperature control are separate and distinct "elements". The Examiner cannot, without specifically pointing to some teaching (*i.e.*, column & line number), that the heaters contemplated in *Lipshutz et al.* and *Anderson et al.* transport fluid in a microchannel. The Examiner is engaging in hindsight and selective element selection to create these improper rejections.<sup>4</sup> In the interest of clarity, the Applicants provide an analysis of *Lipshutz et al.* to demonstrate, moreover, that fluid transport and heating elements are taught as distinct and separate elements.

Finally, *Lipshutz et al.* provides another summary paragraph (col 28 ln 3-23) that describes the above distinct elements operating in combination. The Examiner has improperly referred to this paragraph in *Anderson et al.* at col 35, first paragraph to assert an explicit teaching of differential heating fluid transport (*supra*). The following representative sentences from this paragraph show that fluid transport heating elements are considered separate and distinct:

Thus, in addition to the above described components, the integrated device of the invention will typically incorporate a number of additional components for sample transporting, direction, manipulation, and the like. Generally, this will include, a plurality of micropumps, valves, mixers and heating elements.

*Lipshutz et al.*, col 28 ln 18-23.

The above complete review of *Lipshutz et al.* and analysis of statements in context rebuts the Examiner's unsupported arguments. In conclusion, the Applicants argue that the *Anderson et al.* portfolio does not teach heating elements arrayed along a microchannel in order to transport fluid.

The Applicants, therefore, respectfully request that the Examiner withdraw all rejections based upon anticipation and/or obviousness.

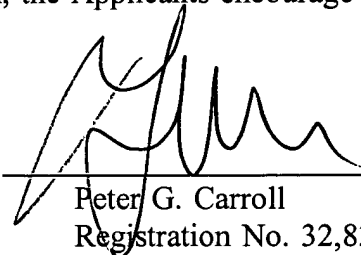
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<sup>4</sup> The Examiner is impermissibly, within the framework of section 103, picking and choosing from *Anderson et al.* only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965).

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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